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# 510(K) SUMMARY

Submitted by:

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| Trade Name: | Alcon Series 20000® LEGACY® Mackool™ System |
| Common Name | Phacoemulsification Tip and Sleeve |
| Classification Name | Phacofragmentation System (per 21 CFR 886.4670) |

## 1. Predicate Device

The currently marketed device(s) to which we are claiming equivalence are:

a. K926512, Storz Modified Phaco Needle with Insulation Sleeve, (Storz Instrument Company)
b. K831836, Epsilon Ultrasonic Tips & Accessories, (CooperVision/Alcon Laboratories)
c. Phacoemulsification tips associated with Alcon's:
K911808, Gemini Ophthalmic Surgery System (Series 20,000® Legacy®)
K861380, Series Ten Thousand Master

## 2. Device Description

The Series 20000 Legacy System and its predicate devices use ultrasonic energy to emulsify cataractous lens material and remove it from the eye (phacoemulsification). Electronic energy is generated in the machine, delivered to a handpiece and converted to ultrasonic energy delivered through a hollow titanium needle, or tip. Irrigation fluid is delivered to the eye via the combination of an irrigation sleeve over the handpiece tip. The emulsified lens material is aspirated out of the eye through the center of the handpiece/tip assembly.

In this new system, an inner protective sleeve has been attached around the barrel of the ultrasonic tip in order to reduce the amount of undesirable heat transferred to the wound site. These ultrasonic tips will be available in three (3) styles each consisting of combinations of two (2) tip diameters and three (3) tip edge bevel angles.

## 3. Intended Use of the Device

The intended use of this device is the automated phacoemulsification of a cataractous natural crystalline lens.

## 4. Summary of the Technological Characteristics of the Device

The Alcon Mackool System Tip Sleeve Combination ( TSC) utilizes the same technology (and patents) as the Storz MicroSeal Ultrasonic Tip Sleeve Combination in that a portion the ultrasonic tip is covered by a thin plastic inner sleeve under the standard infusion sleeve. The inner sleeve reduces the unwanted heat generated, isolates the tip from the incision site, and reduces the chance of corneal burn during surgery. This improvement will also allow surgeons to use smaller surgical incisions, reduce wound leakage, promote a more stable eye chamber, and result in less corneal endothelium hydration

## 5. Summary of the Performance Data

Performance of Alcon's Mackool system TSC's was compared to the predicate devices in three areas; thermal performance, fluidics performance and cutting performance.

Thermal performance was evaluated in bench tests and in post mortem eye tests by using thermocouples to measure the temperature at the wound site in simulated use tests. Alcon Mackool™ tips showed significantly lower temperature than Alcon standard 0.9 mm, and somewhat lower temperature than Storz MicroSeal tips.

Fluidics performance was evaluated by measuring the infusion flow capability of the new device compared to the predicate devices. All TSC were found to have similar flow capability. The clinical relevance of this is that intraocular pressure during phacoemulsification procedures will be similar for all the devices, assuming the same steady aspiration flow rate.

Cutting performance was evaluated in bench tests by measuring tip stroke length and in the clinic by surgeon evaluation. Both tests showed Mackool tips have an acceptable cutting performance which is equal to (Alcon tips) or superior to (Storz tips) the cutting performance of the predicate devices.

The performance testing has shown that Alcon's Mackool system has similar or better thermal, fluidic, and cutting performance than the predicate devices.

## 6. Conclusions

Therefore, based on the data provided in this Premarket notification, the Alcon Mackool System has been proven to be substantially equivalent to predicate devices such as the Storz Modified Phaco Needle with Insulation Sleeve and other devices detailed in Item 1 (above).